

**CONFIDENTIAL & PROPRIETARY / TRADE SECRET**  
**NOT SUBJECT TO DISCLOSURE UNDER THE FREEDOM OF INFORMATION ACT**  
**OR VERMONT PUBLIC RECORDS LAW**

VIA E-MAIL

October 23, 2020

Gilead Sciences, Inc.  
333 Lakeside Drive  
Foster City, CA 94404

Office of the Vermont Attorney General  
Attention: Attorney General, T.J. Donovan  
109 State Street  
Montpelier, VT 05609  
[AGO.highcostprescriptiondrugs@vermont.gov](mailto:AGO.highcostprescriptiondrugs@vermont.gov)

Dear Attorney General Donovan:

This letter provides notice, as required by Section 4637(b) of Vermont Act 193, as codified at 18 VT. Stat. Ann. § 4637 (“Act 193”) that Gilead Sciences, Inc. (“Gilead”) released a new prescription drug to market, VEKLURY® (remdesivir) for injection, for intravenous use, 100 mg of remdesivir as a lyophilized powder, in a single-dose vial (NDC 61958-2901-02) on October 22, 2020, at a wholesale acquisition cost above that of a specialty drug under the Medicare Part D program.


Section 4637 of Act 193 does not currently define “release of the drug in the commercial market.” Further, Gilead is not aware of any guidance issued by the Office of the Attorney General (the “Office”) or any Vermont regulation that defines “release of the drug in the commercial market” for purposes of Section 4637. Gilead interprets “release of the drug in the commercial market” to mean when Gilead makes a drug available for order.

Section 4637 of Act 193 also does not currently define “new prescription drug,” and Gilead is not aware of any guidance issued by the Office or any Vermont regulation that defines “new prescription drug” for purposes of Section 4637. Gilead reasonably assumes that the requirements enumerated in Section 4637 for a “new prescription drug” apply upon receipt of FDA approval of (1) an original New Drug Application, Abbreviated New Drug Application, or Biologics License Application that (2) authorizes the introduction of a new dosage form, as reflected in the new, FDA-approved labeling.

We understand that, pursuant to Section 4637(e) of Act 193, the Office will publish information reported pursuant to Section 4637 on its website. Accordingly, we have attached a single-page

version of this notice the Office can publish on its website while preserving the signatory's right to privacy, consistent with Section 317(c)(10) of Title 1 of the Vermont Statutes Annotated. We ask that the Office only publish the single-page version of this notice on its website, pursuant to Section 4637(e) of Act 193.

Sincerely,

DocuSigned by:  
  
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David Hsu  
Sr. Director, Trade Strategy and Operations

**Notice of New Drug Pursuant to Section 4637 of Vermont Act 193**

This letter provides notice, as required by Section 4637(b) of Vermont Act 193, as codified at 18 VT. Stat. Ann. § 4637, that Gilead Sciences, Inc. released a new prescription drug to market, VEKLURY® (remdesivir) for injection, for intravenous use, 100 mg of remdesivir as a lyophilized powder, in a single-dose vial (NDC 61958-2901-02) on October 22, 2020, at a wholesale acquisition cost above that of a specialty drug under the Medicare Part D program.